March 5, 2009
Great Lakes and Environment Committee
Comments on HB 4402

Ted Schettler MD, MPH
Science and Environmental Health Network
Ann Arbor, MI

Thank you for the opportunity to submit comments in support of HB 4402. I am a physician with a medical degree from Case-Western Reserve University. I also have a degree in public health from Harvard University with training in toxicology and epidemiology. I practiced medicine for 35 years and have served on advisory committees of the US EPA and National Academy of Sciences.

I am the science director of the Science and Environmental Health Network, a non-profit organization that addresses a variety of public and environmental health issues. I am a co-author of three books, Generations at Risk: Reproductive Health and the Environment, In Harm's Way: Toxic Threats to Child Development, and Environmental Threats to Healthy Aging. I have also published papers on related topics in the peer reviewed medical literature.

I wish to make three general points:

1) Lindane is absorbed through the skin and is a persistent, bioaccumulative, toxic pesticide.

2) The FDA agrees with this assessment and, after years of attempting to educate clinicians and patients about how to use lindane, has put a black box warning on the product because of increasing safety concerns.

3) Lindane can not only cause acute neurological symptoms but also interfere with normal neurologic development and can cause permanent changes in the nervous system, even at low doses. Moreover, lindane poses a risk not only to developing children but also to older adults.

Lindane is a toxic chemical that is both persistent and bioaccumulative. It persists for months to years in the environment, resisting degradation. These features are distinctly unlike alternatives to lindane such as permethrin and malathion, which are not persistent in people, wildlife, or the general environment. And, unlike lindane and malathion, permethrin is poorly absorbed through the skin.

Because of its toxic properties and environmental persistence, lindane is no longer used at all in 53 countries and in California. In California, the ban on lindane use resulted in reduction in reported unintentional exposures and did not adversely affect head lice and scabies treatment.

As you know, the Commission for Environmental Cooperation, an international organization created by Canada, Mexico and the United States under the North American Agreement on Environmental Cooperation (NAAEC), is committed to reduce or eliminate all uses of lindane because of its toxicity, environmental persistence, capacity to contaminate food supplies around the world, and large amounts of toxic waste by-products associated with its manufacture. Lindane is also being considered for complete international phase-out under the Stockholm Convention, which is intended to eliminate the use of the most hazardous persistent, bioaccumulative toxic chemicals.

The Federal FDA has control over the use of lindane as a pharmaceutical agent and has shown increasing concern about its safety since it was registered for use. Transcripts of FDA deliberations in the 1980s—available on the FDA website—show that officials wanted to advise against the use of lindane in infants and pregnant and lactating women but were resisted by representatives of Reed and Carnrick, then the drug's sponsor. (http://www.fda.gov/ohrms/dockets/ac/accutane/1782t1a.pdf) At that time and continuing today, the FDA knew that side-effects of lindane, like other drugs, are markedly under-reported and that misuse, including overuse, of the drug is common. The agency held lengthy discussions about how best to educate people, including physicians, about the proper use of lindane. Negotiating with the drug's sponsor at that time, they developed labeling instructions warning people not to use lindane shampoo in the bath or shower, warned against using the lotion after a warm bath or shower, warned against unnecessary skin contact, and said that assistants should wear rubber gloves and other protective clothing. They knew, and know today, that lindane can cause seizures and wondered what lindane might be doing to the brain in people who did not have seizures as an obvious side effect.

Now we know more. Laboratory animal studies in the 1990s (Serrano, 1990; Rivera, 1998) show that lindane interferes with normal brain development. In people, brain development begins soon after conception and continues through infancy, childhood, and adolescence. Laboratory animals given doses of lindane lower than those required to produce hyperactivity, seizures, or other evidence of obvious toxicity show permanent alteration of behavior, brain chemistry, and brain architecture, including interference with laying down essential myelin coating onto nerve fibers in the brain. A recent animal study also shows that low level lindane exposures during development cause permanent changes in detoxifying enzyme concentrations in the liver and brain. (Johri, 2008). Collectively, these data show that the developing brain is more sensitive to lindane than the adult and that exposures during development can cause long-lasting effects. Indeed, the warning on lindane says that the immature central nervous system may have increased susceptibility to the effects of the drug, based on animal testing at levels of exposure close to those expected in people who use lindane lotion to treat scabies. Based on animal testing data, we can conclude that brain development in people is subject to disruption by lindane exposures from the time of conception through adolescence when most myelination is completed.

Beyond this, we now know that we should also consider the impacts of lindane later in life. Lindane disappears from the blood within hours but it is not gone from the body. Rather, because lindane is fat soluble, it is deposited in tissues and organs with high fat content. Lindane in the blood or urine is only a reflection of recent exposures—not total exposures that have occurred in the past. Because of its high fat content, the brain is one of the repositories where lindane can linger for many days and very likely for much longer.

An autopsy study of people with Parkinson's disease published in 2000 reported significantly higher levels of lindane in the area of the brain involved in that disease (substantia nigra) than in a control group. (Corrigan, 2000) This study is consistent with a large body of evidence linking pesticide exposures to an increased risk of Parkinson's disease.

A 2007 study compared lindane with permethrin with respect to their ability to cause oxidative stress in adult scabies patients. (Oberoi, 2007) Oxidative stress is a phenomenon involving production of reactive molecules that cause diffuse damage to cells through a variety of mechanisms. Oxidative stress is generally accepted as playing an important role in Parkinson's disease, among others. Patients were alternatively assigned to treatment by either lindane lotion or permethrin cream. Blood samples were collected before and after the application of the drugs and evaluated for oxidative stress parameters and compared with healthy controls. Every parameter studied showed that lindane caused more oxidative stress than permethrin. The authors concluded that topical application of lindane induced significant oxidative stress as compared to permethrin which appears to be a safer option for the treatment of scabies.

Acute side effects of lindane, such as dizziness and seizures, are quite obvious and can be fairly easily linked to use of the drug. But subtle impacts on brain development or impacts that may not become apparent for years are an entirely different matter. Animal tests and epidemiologic studies in people clearly demonstrate increased risks, but we will never know the extent to which lindane may have those kinds of effects in any individual person.

If adopted, this bill would not ban the use of lindane. Rather, it would require that if a physician believes that lindane is necessary, after other measures have failed, then he or she should supervise its use in order to minimize the risk of misuse or excessive exposure. The medical and public health communities are in support of this bill. Your vote in favor of the bill would help to protect children and adults from unnecessary exposures to this neurotoxin and environmental contaminant.

Corrigan F, et al. Organochlorine insecticides in substantia nigra in Parkinson's disease. J Toxicol Environ Health A. 59(4), 2000

Johri et al. Persistence in alterations in the ontogeny of cerebral and hepatic cytochrome P450s following prenatal exposure to low doses of lindane. Toxicol Sci 101(2), 2008.

Oberoi S, et al. Comparative effect of topical application of lindane and permethrin on oxidative stress parameters in adult scabies patients. Clin Biochem 40(16-17), 2007.

Rivera et al. Behavioral and monoaminergic changes after lindane exposure in developing rats. Neurotoxicol Teratol 20(2), 1998.

Serrano et al. Effect of lindane on the myelination process in the rat. Neurotoxicol Teratol 12, 1990.

Michigan Network for
CHILDREN'S
Environmental
HEALTH

Supporters of banning or restricting the use of pharmaceutical lindane in Michigan

1. Michigan Chapter of the American Academy of Pediatrics
2. Michigan Nurses Association
3. Michigan Council of Nurse Practitioners
4. Michigan Association of School Nurses
5. Michigan Council for Maternal And Child Health
6. Michigan Pharmacists Association
7. Wayne County Medical Society of Southeast Michigan

The Michigan Network for Children's Environmental Health, which includes:

- American Academy of Pediatrics (Michigan Chapter)
- Arab Community Center for Economic and Social Services (ACCESS)
- Association for Children's Mental Health
- Autism Society of Michigan
- Citizens for Alternatives to Chemical Contamination
- Clean Water Fund
- Clinton County Family Resource Center
- Detroiters Working for Environmental Justice
- East Michigan Environmental Action Council
- Ecology Center
- Healthy Homes Coalition of West Michigan
- Learning Disabilities Association (LDA) of Michigan
- Local Motion
- Michigan Coalition for Children and Families
- Michigan Council for Maternal and Child Health
- Michigan Environmental Council
- Michigan League of Conservation Voters Education Fund
- Michigan Nurses Association
- Science and Environmental Health Network
- Voices for Earth Justice

American Academy of Pediatrics

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Beatrice Murray, M.D.
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Michigan Chapter

Michigan Chapter of American Academy of Pediatrics promotes banning of Lindane for pharmaceutical treatment of lice and scabies in children.

September 28, 2005

The Michigan Chapter of the American Academy of Pediatrics (MIAAP) is a diverse group of over 1,700 pediatricians. Our members are active in promoting the health and well being of the children of the state of Michigan.

As health care providers, we support a ban on the pharmaceutical use of Lindane to treat childhood lice and scabies. Lindane is readily absorbed into the body upon exposure, and can cause toxicity to the nervous system. The IARC considers it a "possible carcinogen". The FDA recommends Lindane be used with extreme caution on individuals less than 110 pounds; and an FDA database reported adverse effects from use of Lindane in accordance with directions.

Safer alternatives can easily replace this poison. There are less toxic and more effective treatments available, including non-chemical options.

Lindane also poses an environmental threat because it is a persistent, bioaccumulative toxin. One dose of Lindane can contaminate six million gallons of water, and is expensive and difficult to remove. Small amounts of Lindane are acutely toxic and can be lethal when ingested.

As pediatricians, we work daily to promote the health and safety of Michigan's children. A ban on the use of Lindane will eliminate children's exposure to an acutely toxic compound. Due to Lindane's negative health impacts and environmental contamination, the compound has already been banned in more than 50 countries and in the state of California.

We urge our state legislature to act on behalf of Michigan's children, and protect them from exposure to this dangerous compound by passing a ban on the pharmaceutical use of Lindane in Michigan.

Submitted on behalf of MIAAP by:

Sheila Gahagan, MD, MPH

President, Michigan Chapter of American Academy of Pediatrics

Michigan Nurses Association

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March 3, 2006

The Michigan Nurses Association (MNA) supports the banning of Lindane for the pharmaceutical treatment of lice and scabies in children.

Lindane is readily absorbed into the body upon exposure, and causes acute toxicity to the nervous system. The United States Environmental Protection Agency considers Lindane a "possible carcinogen." The Food and Drug Administration reports adverse effects from the use of Lindane in accordance with directions.

Lindane also poses an environmental threat because it is a persistent, bioaccumulative toxin. One dose of Lindane can contaminate six million gallons of water, and it is expensive and difficult to remove. Small amounts are acutely toxic and can be lethal if ingested.

As nurses, we work daily to promote the health and safety of Michigan's public. A ban on the use of Lindane will eliminate the public's exposure to another acutely toxic compound. Due to Lindane's negative health impacts and environmental contamination, it has been banned in more than fifty countries and in the State of California.

Other safer alternatives can easily replace this poison. There are less toxic and more effective treatments available, including non-chemical options.

We strongly urge our state legislature to act on behalf of the Michigan public and protect it from exposure to this dangerous compound by passing a ban on the pharmaceutical use of Lindane in Michigan.

Sincerely,

Tom Bissonnette

Tom Bissonnette MS, RN
MNA Executive Director

Michigan Council of Nurse Practitioners

WHEREAS in the year 2003 the Food and Drug Administration (FDA) issued a Public Health Advisory regarding the topical use of Lindane Lotion and Lindane Shampoo which included a boxed warning highlighting safety issues concerning these products and recommending that they only be used as second-line agents for the treatment of scabies and lice[1]

WHEREAS in the United States up to 1 million prescriptions are written for Lindane products each year to treat head lice and scabies[2]

WHEREAS Lindane has several potential serious adverse effects including neurotoxic symptoms ranging from dizziness and headache to seizure and death[3]

WHEREAS up to 20 percent of serious adverse effects occur in patients using the product appropriately [3]

WHEREAS children are at higher risk to develop life-threatening adverse reactions to Lindane and scabies and head lice primarily occur in the pediatric population

WHEREAS Lindane has no greater efficacy than other safer available pharmaceutical agents[4]

The Michigan Council of Nurse Practitioners hereby resolves to support legislative policies to ban the pharmaceutical use of Lindane

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[1] *FDA Talk Paper*. http://www.fda.gov/bbs/topics/ANSWERS/2003?ans01205.html

[2] *Lindane Shampoo and Lindane Lotion Questions and Answers.* Rockville (MD): Center for Drug Evaluation and Research, US Food and Drug Administration; 2003. www.fda.gov/cder/drug/infopage/lindane/lindaneQA.htm

[3] *FDA Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice*. Rockville (MD): Center for Drug Evaluation and Research, US Food and Drug Administration: 2003. www.fda.gov/cder/drug/infopage/lindanePHA.htm

[4] *Interventions for Treating Head lice* (Cochrane Review): The Cochrane Library, Issue 3, 2005. http://www.update-software.com/Abstracts/ab001165.htm

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Julia Lechtenberg
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September 13, 2007

Dear Representative Hammon,

The Michigan Association of School Nurses (MASN) recognizes the direct correlation between health and learning. School Nurses advance the well-being, academic success and life-long achievement of students by promoting the health and well being of children in the state of Michigan. I am writing to express support for House Bill 4569, which would phase out the use of lindane in pharmaceutical products in Michigan.

Lindane is a prescription medication that is used topically for the treatment of head and body lice and scabies. Used improperly, lindane can have toxic effects. Research indicates that most of the serious adverse events reported with lindane products are due to misuse and overuse. House Bill 4569 directly impacts the health and well being of children in Michigan by limiting the opportunity for misuse of lindane. MASN supports the intent of House Bill 4569.

Sincerely,

Julia Lechtenberg RN

Julia Lechtenberg, RN, MSN, NCSN
MASN President

MICHIGAN COUNCIL FOR
MATERNAL AND CHILD HEALTH

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PAUL N. SHAHEEN
Executive Director

Michigan Council for Maternal and Child Health promotes a phase out of Lindane as a pharmaceutical treatment of lice and scabies.

The Michigan Council for Maternal and Child Health (MCMCH) is MCMCH is a maternal and child health advocacy group in Michigan. For nearly two decades MCMCH has educated and informed those in government who make laws, write regulations, and implement policies affecting the health of babies, children, and their mothers.

As health advocates, we support a phase out on the pharmaceutical use of Lindane to treat childhood lice and scabies. Lindane is readily absorbed into the body upon exposure, and can cause can cause numbness, motor restlessness, anxiety, tremors, cramps and seizures. The IARC considers it a "possible carcinogen". The FDA recommends Lindane be used with "extreme caution" on individuals less than 110 pounds. In the FDA's Adverse Event Reporting System, 20% of those reporting serious health effects due to lindane used the product according to the directions.

Safer alternatives can easily replace this toxic compound. There are less toxic and more effective treatments widely available, including non-chemical options.

Lindane also poses an environmental threat because it is a persistent, bioaccumulative toxin. One dose of Lindane can contaminate six million gallons of water, and is expensive and difficult to remove. Small amounts of Lindane are acutely toxic and can be lethal when ingested.

As child health advocates, we work daily to promote the health and safety of Michigan's children. A phase out of Lindane will eliminate children's unnecessary exposure to an acutely toxic compound. Due to Lindane's negative health impacts and environmental contamination, the compound has already been banned in more than 50 countries and in the state of California.

We urge our state legislature to act on behalf of Michigan's children, and protect them from exposure to this dangerous compound by passing a phase out on the pharmaceutical use of Lindane in Michigan.

Submitted on behalf of MCMCH by:

Paul Shaheen, President, Michigan Council for Maternal and Child Health

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April 11, 2006

William B. Weil, MD
Michigan Environmental Health Network
528 East Oakwood Drive
East Lansing, MI 48823

Dear Dr. Weil:

The Michigan Pharmacists Association (MPA) actively promotes patient safety and supports the campaign initiated by the Michigan Environmental Health Network (MEHN) that will establish a ban on the pharmaceutical use of Lindane to treat childhood lice and scabies.

MPA strongly supports protecting Michigan's children from exposure to this dangerous compound by passing a ban on the pharmaceutical use of Lindane in Michigan. MPA looks forward to promoting the efforts of MEHN to our members.

Sincerely,

Larry D. Wagenknecht, Pharmacist
Chief Executive Officer

mga

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February 24, 2006

William B. Weil, MD
528 East Oakwood Dr.
East Lansing, MI 48823

Dear Doctor Weil:

I am writing in response to your letter regarding Lindane and your campaign to protect children's health. Thank you for informing us on the dangers of the use of Lindane shampoos and lotions on children in the treatment of head lice and scabies.

The Wayne County Medical Society of Southeast Michigan gladly endorses your efforts.

Sincerely,

Adam Jablonowski
Executive Director

Legislative Testimony

Michigan Great Lakes and Environment Committee
May 7, 2008

Dr. Jonathan Fliegel, M.D.
Pediatrician, St. Joseph Mercy Health System
Chair, Legislative Committee, 2005-2008
Michigan Chapter, American Academy of Pediatrics

We strongly support HB 4569, allowing the use of lindane only in the physician's office under a physician's supervision

The Michigan Chapter of the AAP has a long history of concern and interest in lindane and other toxic chemicals that affect children's health.

- Chapter membership includes more than 1700 pediatricians in our state
- Numerous pediatricians have advocated locally, and at the state and national level
- More than 10 years of concern and actions regarding lindane specifically from Drs. William Weil, Sheila Gahagan, recently myself and many others
- During the past 3 years, our membership and board has repeatedly stressed our support for this legislative action.

Concern about lindane and the genesis of this bill began with citizens, NOT with the legislature.

- Pediatricians helped organize a statewide conference, which brought many concerned citizens together. MNCEH grew out of this collaboration.
- We contacted others to work with us—nurses, pharmacists, school nurses, MDCH-- and to gather support for our legislative issues, including our proposals on lindane.
- So instead of a "slippery slope" with the legislature regulating physicians' practices, this is instead the opposite—physicians and other citizens approaching the legislature to pass a law that we feel can improve children's health.

Our concerns about lindane arise from the following:

- Scabies and head lice are nuisances, but in our experience do not cause serious disease in Michigan.
- Several safer alternatives exist. The FDA labeled lindane as a second line therapy in 1995 because of concerns for greater potential for serious adverse events compared to other alternatives.
- Lindane is the only pharmaceutical in its class (to treat scabies and head lice) that has received a Black Box warning (in 2003).
- There is more resistance of mites and lice to lindane than to other alternative pharmaceuticals, which makes lindane less effective as a treatment.
- We have not seen or documented problems of worsening head lice or scabies disease when lindane use has decreased (for Michigan Medicaid patients from 2004-2008) or when it has been banned (California in 2002, and in more than 50 countries).
- Adverse effects from lindane continue to be reported in Michigan.
- Given the magnitude and priority of their other issues, we do not expect that the FDA will act further on lindane in the near future.

We believe that limiting the administration to a physician's office can improve safety and decrease adverse effects.

- We feel that the benefit of safety more than outweighs the inconvenience of treatment in the office.
- Shampooing would take less time than breathing treatments given for wheezing
- Physician billing is based on either complexity or time.

HB 4569 is NOT a ban, and thus does not take any treatment options away from physicians in Michigan. We feel that it is an adjunct to the FDA Warning that is already in place.

BARBARA BOXER
CALIFORNIA

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March 17, 2005

Lester M. Crawford
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Stephen Johnson
Acting Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, DC 20460

Dear Acting Administrator Johnson and Acting Commissioner Crawford,

I am writing to urge your agencies to support eliminating the use of the pesticide lindane at the upcoming meeting of the Lindane Task Force under the Commission on Environmental Cooperation. It is in the best interest of our nation's public health to ban all uses of lindane in the United States.

Lindane is an acutely toxic pesticide. It can cause cancer, seizures, and damage to the nervous system and it can also disrupt the human hormone system. Despite these dangers, lindane use continues in this country, both in agriculture and as an ingredient in pharmaceutical products. In addition to the direct exposure risks from pharmaceutical treatments and exposures in agriculture, lindane and its by-products pose a long term risk to human health and the environment. Recent studies have concluded that 62 percent of U.S. residents have toxic by-products of lindane in their bodies.

Pharmaceutical uses in lindane have already been successfully banned in California, and state legislation pending in New York and Illinois would do the same. The European Union and Canada have banned all agricultural uses of lindane. In addition, Mexico has recently decided to phase out all uses of lindane. While more than 50 counties have banned uses of lindane, the United States continues to allow the use of this harmful pesticide. Alternatives for all uses are available, and it is time for this dangerous chemical to be taken completely off the market.

I strongly urge you to phase-out all uses of lindane in the United States.

Sincerely,

Barbara Boxer
United States Senator

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California State Senate

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NATURAL RESOURCES AND WATER
ENVIRONMENTAL QUALITY

May 31, 2006

Representative Edward Gaffney
S0585 House Office Building
P.O. Box 30014
Lansing, MI 48909-7514

Dear Representative Gaffney:

As the legislator who sponsored the California pharmaceutical lindane ban, I am writing to express support for a similar bill in the state of Michigan (HB 5574). As you may know, the bill to ban pharmaceutical lindane was introduced into the California Assembly in early 2000 (AB 2318), and passed both the Senate and the Assembly later that year. We have enclosed a copy of the legislation with this letter.

Action to ban pharmaceutical lindane in California began in 1998, when new water quality standards for lindane were adopted in California. According to data from the Los Angeles County Sanitation District, lindane discharges in municipal water systems in Los Angeles County greatly exceeded these limits, and they estimated that one dose of lindane shampoo was contaminating up to six million gallons of water. The District calculated that a single dose of lindane was costing the city $4,000 to remove it from water systems.

In addition to environmental concerns, the bill was passed because lindane poses a health risk to citizens. Lindane exposure can cause severe neurologic effects, especially in children. The California Department of Health Services stated, "Given that 1 percent Lindane shampoo is less effective and has more potential toxicity than the easily available alternatives, there is no reason to continue prescribing this material for the control of head lice in California."

After the California ban went into effect in 2002, lindane water contamination levels dropped dramatically, down from a high of 40 ppt to less than 2.5 ppt by 2005, with zero detects in 2006 as of April. The prescribing practices of physicians changed without consequence, with no negative impacts reported by the medical community. Prison medical personnel report that lindane-free treatment for scabies have been satisfactory.

I believe legislative action on lindane in Michigan would have similar positive impacts on public health and environmental protection in your State.

Regards,

Senator Alan Lowenthal

Department of Health and Human Services

Public Health Service
Food and Drug Administration

Silver Spring, MD 20993

TRANSMITTED BY FACSIMILE

Kurt Orlofski
CEO
Morton Grove Pharmaceuticals, Inc.
6451 West Main Street
Morton Grove, IL 60053

RE: ANDA # 88-191
Lindane Shampoo, USP, 1%
MACMIS ID # 15909

WARNING LETTER

Dear Mr. Orlofski:

This letter notifies Morton Grove Pharmaceuticals, Inc. (Morton Grove) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed promotional pieces for Lindane Shampoo, USP, 1% (Lindane Shampoo) issued by Morton Grove and by Alliant Pharmaceuticals, Inc. (Alliant), which until recently marketed Lindane Shampoo on behalf of Morton Grove.[1] These pieces include websites promoting Lindane Shampoo (http://www.alliantpharma.com/alliant_products.html and http://www.lindane4lice.com) [2] and a promotional piece entitled *The Nit Picking News* (LINS 06-602). The websites and newsletter are misleading in that they omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo, particularly in pediatric patients; include a misleading dosing claim; and overstate the efficacy of Lindane Shampoo. In particular, Lindane Shampoo is plainly labeled as second line treatment, suitable only when other, safer treatments fail or are not tolerated. The materials convey little sense of this limitation and little about the magnitude and nature of the risks associated with the drug. The materials appear to represent an attempt to downplay the significant risks associated with Lindane Shampoo use and encourage wider use, with less care, than is appropriate under approved labeling. These websites and newsletter thus misbrand Lindane Shampoo in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 352(a) & (n) and 321(n), and FDA's implementing regulations. See 21 CFR 202.1(e)(3)(i); (e)(5); (e)(6)(i), (e)(7)(viiii), & (e)(7)(x). We are very concerned about the potential for significant negative health consequences in children who use Lindane Shampoo because you are promoting Lindane Shampoo as being safer and more effective for pediatric patients than has been demonstrated by substantial evidence or substantial clinical experience, despite the boxed warning in Lindane Shampoo's FDA-approved product labeling (PI), and FDA's March 2003 Public Health Advisory [3] and Talk Paper[4] describing the risk of severe neurotoxicity in patients, including children, who weigh less than 110 pounds (50 kilograms).

Furthermore, while *The Nit Picking News* was submitted to FDA by Morton Grove under cover of Form FDA-2253, neither of the two websites were submitted to FDA under cover of Form FDA-2253, as required by 21 CFR 314.81 (b)(3)(i).

Background

The Indications and Usage section of the PI states (in relevant part):

> Lindane Shampoo is indicated for the treatment of head lice (infestations of *Pediculosis humanis capitis*), crab lice (infestations of *Pthirus pubis*), and their ova only in patients who
>
> 1. cannot tolerate other approved therapies, or
> 2. have failed treatment with other approved therapies.
>
> Lindane Shampoo should be used in the context of an overall lice management program that includes:
>
> • Visual inspection to ensure that the patient is currently infested with live lice (empty egg casings or "nits" can remain on hair shaft long after true infestation).
>
> • Manual removal of nits using a comb designed for this purpose and/or individual removal with tweezers followed by close examination of the hair and scalp.
>
> • Evaluation and treatment of sexual contacts simultaneously. Sexual contacts should be prescribed Lindane Shampoo only if they either have failed to respond to adequate doses of other approved therapies or are intolerant of other approved therapies.
>
> • All recently worn clothing, underwear, pajamas, used sheets, pillow cases, and towels should be washed in very hot water or dry-cleaned.

The PI for Lindane Shampoo includes a boxed warning relating to the risk of neurotoxicity associated with the use of this product. The boxed warning states:

> **WARNINGS:**
> Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice. (See INDICATIONS AND USAGE.)
>
> **Neurologic Toxicity**
> Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions. Lindane Shampoo should be used with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.
>
> **Contraindications**
> Lindane Shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.
>
> **Proper Use**
> Instruct patients on proper use of Lindane Shampoo, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for retreatment with Lindane Shampoo. (See DOSAGE AND ADMINISTRATION.)

The Contraindications section of the PI states (in relevant part):

> Lindane Shampoo is contraindicated for premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane.
>
> Lindane Shampoo is also contraindicated for patients with crusted (Norwegian) scabies and other skin conditions (e.g. atopic dermatitis, psoriasis) that may increase systemic absorption of the drug.
>
> Lindane Shampoo is contraindicated for patients with known uncontrolled seizure disorders and for individuals with a known sensitivity to the product or any of its components.

The Warnings section states (in relevant part):

> Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions.
>
> There have been cases of adverse events reported for Lindane Shampoo and Lindane Lotion in which a serious outcome (hospitalization, disability or death) has occurred. In approximately 20% of these cases, the shampoo and lotion were reported to have been used according to the labeled directions. Of these cases, thirteen deaths were reported, many of which were remote from the time of actual Lindane use. Lindane toxicity, verified by autopsy was the cause of one infant's death, and was the cause of death reported for an adult in a successful suicide. The direct causes of death for the other cases were attributed to reasons other than lindane. Most of these adverse events occurred with Lindane Lotion.
>
> Infants, children, the elderly, and individuals with other skin conditions and those who weigh <1101bs (50 kg) may be at a greater risk of serious neurotoxicity. (See Pediatric Use and Geriatric Use.) Animal studies have shown increased susceptibility to neurologic adverse events in younger animals. Children have a larger body surface area to volume ratio that may result in a proportionately larger systemic exposure.
>
> Careful consideration should be given before prescribing Lindane Shampoo to patients with conditions that may increase the risk of seizure, such as HIV infection, history of head trauma or a prior seizure, CNS tumor, the presence of severe hepatic cirrhosis, excessive use of alcohol, abrupt withdrawal from alcohol or sedatives, as well as concomitant use of medications known to lower seizure threshold. (See PRECAUTIONS: Drug Interactions)
>
> Patients should be instructed on the proper use of Lindane Shampoo, especially the amount to apply, how long to leave shampoo on, and the need to avoid retreatment. Patients should be informed that itching may occur after the successful killing of lice and repeat treatment may not be necessary.

The Precautions section of the PI includes the following directions (in relevant part) under "Information for Use":

> • Use only enough Lindane Shampoo to lightly coat the hair and scalp.
>
> • Apply shampoo directly to dry hair without adding water. Work thoroughly into the hair and allow to remain in place for 4 minutes only. Special attention should be given to the fine hairs along the neck and behind the ears.
>
> • After 4 minutes, add small quantities of water to hair until a good lather forms.
>
> • Immediately rinse all lather away. Avoid unnecessary contact of lather with other body surfaces.
>
> • Towel briskly and then remove nits with nit comb or tweezers.
>
> • There may be some Lindane Shampoo left in the bottle. Close the bottle with the leftover Lindane Shampoo and immediately throw away the bottle in a trash can out of the reach of children.
>
> • Wash all recently worn clothing, underwear and pajamas, hats, and used sheets, pillow cases, and towels in very hot water or dry-clean.

The Nursing Mothers section of the PI states:

> Lindane is lipophilic and is present in human breast milk, but exact quantities are not known. There may be a risk of toxicity if lindane is ingested from breast milk, or from skin absorption from mother to baby in the course of breastfeeding if Lindane Shampoo is applied topically to the chest area. Nursing mothers who require treatment with Lindane Shampoo should be advised of the potential risks

> and be instructed not to use the product on the skin as would be done for treatment of scabies. They should also be counseled to interrupt breastfeeding, with expression and discarding of milk, for at least 24 hours following use.

The Pediatric Use section of the PI states (in relevant part):

> Infants and children may be at an even higher risk due to immaturity of organ systems such as skin and liver. Lindane Shampoo should be used with caution in patients who weigh less than approximately 110 lbs (50 kg) and especially in infants. Lindane Shampoo is indicated only for the treatment of lice; patients with scabies should use Lindane Lotion according to the labeled instructions.

Coinciding with the addition of the boxed warning to the PIs for Lindane Shampoo and Lindane Lotion, FDA released a Public Health Advisory in March 2003, addressing the significant potential toxicity associated with the use of topical formulations of Lindane Lotion for the treatment of scabies and Lindane Shampoo for the treatment of lice. An FDA Talk Paper was released at the same time on this topic discussing the significance of this risk from a public health perspective given the prevalence of head lice and scabies, which occur mostly in school-aged children.

These significant risks are further emphasized in the Medication Guide for Lindane Shampoo. The Medication Guide is a labeling feature reserved for products that the FDA determines pose a serious and significant public health concern requiring distribution of FDA-approved patient information.

Omission/Minimization of Risk Information

Promotional materials are misleading if they fail to reveal material facts with respect to consequences that may result from the use of the drug as recommended or suggested by the materials. Promotional materials also are misleading if they fail to include a balanced presentation of information relating to risks associated with the use of a drug along with the presentation of promotional claims relating to the effectiveness of the drug. The websites promoting Lindane Shampoo and the mailing piece are misleading because they make prominent claims of effectiveness for Lindane Shampoo for the treatment of head lice in children but omit and/or minimize important risk information from the body of the pieces, including crucial facts about potentially fatal risks associated with the use of Lindane Shampoo in this vulnerable population. This omission of risk information is completely at odds with the current labeling for Lindane Shampoo, which describes a drug associated with potentially fatal risks.

The Alliant "Our Products" web page is misleading in failing to include **any** risk information regarding treatment with Lindane Shampoo, and in failing to note that it is indicated as a second line therapy. One of the principal messages of this web page is that Lindane Shampoo offers safe and effective treatment for head lice in all children, a message plainly at odds with labeling. For example, this product page prominently displays the tagline, "It's more than just CARING - It's caring about OUR KIDS' HEALTH" (emphasis original).

In fact, as stated in its PI, Lindane Shampoo should be used with caution in children because its use has been associated with seizures and death, and because of this risk it is second line treatment. Neither this risk nor any other risk information for the drug is disclosed anywhere on this website. Although the "Our Products" web page states, "Please see black box warning and other important safety information by clicking on the link below." this statement fails to provide appropriate qualification or pertinent information for the claims made on the website and the link to a separate website does not mitigate the misleading omission of risk information from this website. We are particularly concerned that this web page makes claims about improving the lives of children such as the above, yet fails to warn that children can die from using Lindane Shampoo.

Similarly, the Lindane Shampoo website home page and the linked web pages entitled "About Lindane Shampoo" and "Patients & Parents," focus on the use of Lindane Shampoo for pediatric patients. Specifically, the Lindane Shampoo website includes the smiling faces of two children on each web page, and both the content and title of the "Patients and Parents" page promotes use of the drug in children, for example, by stating, "The overwhelming majority of these infestations occur in children from 3 to 15 years of age." These web pages fail to include information on the risks associated with the use of Lindane Shampoo, and completely omit risks associated with the use of Lindane Shampoo in children. Although the "Patients and Parents" web page states: "It is important to follow the directions from the physician closely as in most cases these medications

contain pesticides which if used or administered incorrectly may cause harm. Patients who are pregnant or breast feeding must alert their doctor as some products may not be suitable for their treatment." this page fails to include other important risk information, including the risks associated with the use of this product in patients who weigh less than 110 pounds (50 kilograms). There are links on the "About Lindane Shampoo" and "Patients and Parents" web pages to a PDF document entitled "Medication Instruction Guide" (LINS222 05/05), which contains some risk information, but the link to this document does not mitigate the misleading omission of risk information from these web pages.

Furthermore, your "Medication Instruction Guide" is itself misleading because it fails to present risk information with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of Lindane Shampoo, and fails to reveal material facts with respect to consequences that may result from the use of Lindane Shampoo as recommended. This document presents application instructions using bolded headers and colorful graphics but presents risk information on the bottom right hand side of the web page in very small font. Furthermore, the document omits additional, important risks associated with Lindane Shampoo. For example, it fails to convey that a patient should not use Lindane Shampoo while breastfeeding as it is present in human breast milk and may cause toxicity if ingested from breast milk. The PI states that nursing mothers who require treatment with Lindane Shampoo should pump their breast milk and discard it for at least 24 hours after using the drug.

In addition, we note that, while the boxed warning about Lindane Shampoo does appear on the linked web pages entitled "Healthcare Professionals" and "Important Safety Information," these pages fail to disclose other important risk concepts not covered in the boxed warning, including but not limited to, the contraindications in patients with crusted (Norwegian) scabies and other skin conditions (e.g. atopic dermatitis, psoriasis). While there is a link to the PI on the "Healthcare Professionals" web page, this link does not mitigate the misleading omission of important risk information on these pages. Finally, some of the included risk information is incorrect. Specifically, these web pages state that Lindane Shampoo is contraindicated in "individuals with known ***controlled*** seizure disorders" (emphasis added). In fact the contraindication in the PI is for individuals with "known ***uncontrolled*** seizure disorders" (emphasis added).

Finally, the mailing piece entitled *The Nit Picking News*, which is directed at school nurses, fails to reveal material facts with respect to consequences that may result from the use of Lindane Shampoo as recommended or suggested in the material. In the box entitled "LINDANE facts," the *Nit Picking News* has a bullet which states, "FDA has determined that Lindane products have benefits that outweigh risks when used as directed. **Most serious adverse events reported in association with lindane products have been due to misuse.**" (emphasis original, footnote omitted) This bulleted statement is quoted from a paragraph of FDA's March 28, 2003, Public Health Advisory and cites to this advisory; however, this paragraph of the Public Health Advisory goes on to state:

> **However, there have been rare case reports of serious reactions with apparently normal use. These reports highlight the need to emphasize the potential toxicity of Lindane in the product labels and educate healthcare providers and patients about the risks and how to minimize them, as well as to develop mechanisms to facilitate safe use, once the drug is dispensed to patients. These mechanisms include having Lindane products available only in small packaged amounts to avoid excess application and requiring that the Medication Guide be given to the patient by the pharmacist with each new prescription.** 5(Emphasis original.)

This mailing piece thus omits critical information reflected in the Public Health Advisory and in the PI for Lindane Shampoo regarding the risks of the drug associated with normal use (which include seizures and death). We note that the boxed warning is presented below the "LINDANE facts" box across the bottom of pages two and three of the piece; this, however, is not sufficient to overcome the misleading suggestion created by this claim that serious adverse reactions will not occur when Lindane Shampoo is used as directed.

Misleading Dosing Claim

The promotional piece entitled *The Nit Picking News* includes the claims:

- Effective treatment with any good pediculicide requires at least two treatments 5

to 7 days apart, to assure that both adult lice and eggs are killed by the treatment.

• Regardless of what treatment you choose, the most important "rules" to follow when trying to cure head lice are. . .Retreat in 5-7 days (one treatment will not cure).

These dosage recommendations contradict the PI and the Medication Guide, and are extremely alarming given that re-treatment with Lindane Shampoo can lead to increased exposure and possibly death. The boxed warning in the PI states, "Instruct patients on proper use of Lindane Shampoo, the amount to apply, how long to leave it on, and avoiding re-treatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for retreatment with Lindane Shampoo." The Dosage and Administration section states, "Do not retreat." and the Medication Guide states, "Do not use Lindane Shampoo more than 1 time to treat an attack of lice. Do not use Lindane Shampoo to treat a second attack that comes soon after the first episode. No one knows a safe time to reuse Lindane Shampoo." These claims are particularly concerning given that the risk of neurotoxicity is amplified in many school aged children, the patient population you are targeting in this promotional piece directed at school nurses, because of their larger body surface area to volume ratio.

Overstatement of Efficacy

The Lindane Shampoo website implies that a patient can treat head lice quickly with Lindane Shampoo. For example, it claims:

• Lindane Shampoo is a highly effective topical prescription product for head lice that works in **JUST 4 MINUTES!**

• Lindane Shampoo has a FAST treatment time for head lice. . .it works in just 4 MINUTES! (Emphasis original)

These claims misleadingly suggest that patients utilizing Lindane Shampoo will achieve treatment success in only four minutes. However, treatment of head lice includes considerably more effort than just a four minute application of Lindane Shampoo. As clearly stated in several parts of the PI (see Background section) and the Medication Guide, Lindane Shampoo should be used in the context of an overall lice management program that includes a four minute application time for Lindane Shampoo in combination with towel drying, manual removal of nits using a nit comb or tweezers, and washing of all recently worn clothing, underwear, pajamas, used sheets, pillowcases, and towels. A lice management program is an extremely time consuming and very labor intensive process. Simply applying Lindane Shampoo for four minutes will not successfully treat the infestation. Therefore, these claims overstate the effectiveness of Lindane Shampoo by suggesting that Lindane Shampoo treats head lice in just four minutes.

The "Our Products" page on the Alliant Website claims, "Lindane Shampoo has shown an efficacy rate of 92% at seven days and 85% at 14 days." (footnote omitted) This claim cites to an article that was published in the *American Journal of Diseases of Children* in 1986.[6] However, as observed with antibiotic use and the development of resistant bacteria over time, Lindane use over several decades has helped to select resistant lice which are more difficult to treat successfully today than at the time this study was published in 1986.[7] Recent reviews consistently include comments such as "Resistance to lindane is widespread and has resulted in decreased efficacy in the United States."[8] It is our understanding that efficacy of Lindane has waned over time because of the increasing resistance of lice to this drug. If you have other, more recent data to support these claims, please submit them to FDA for review.

Failure to Submit

FDA regulations require the applicant to submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use) and is required to include a copy of the product's current professional labeling. Neither the Alliant product web page (http://www.alliantpharma.com/alliant_products.html) nor the Lindane Shampoo website (http://www.lindane4lice.com) were submitted to FDA on Form FDA-2253, as required by 21 CFR 314.81(b)(3)(i).

Conclusion and Requested Action

For the reasons discussed above, the websites and newsletter misbrand Lindane Shampoo in violation of the Act and FDA's implementing regulations. 21 U.S.C. 352(a) & (n); 321(n); see also 21 CFR 202.1 (e)(3)(i); (e)(5); (e)(6)(i); (e)(7)(viii) & (e)(7)(x). Finally, the websites were not submitted to FDA under cover of FDA Form-2253, as required by 21 CFR 314.81(b)(3)(i).

DDMAC requests that Morton Grove, and any third party marketing Lindane on behalf of Morton Grove, immediately cease the dissemination of violative promotional materials for Lindane Shampoo such as those described above. We are extremely concerned by this promotion, which targets pediatric patients who are at particular risk with respect to this drug.

Please submit a written response to this letter on or before December 31, 2007, stating whether you intend to comply with the above request, listing all violative promotional materials for Lindane Shampoo the same as or similar to those described above, and explaining your plan for discontinuing use of these materials. Because the violations described above are serious, we request, further, that your submission include a comprehensive plan of action to disseminate truthful, non-misleading, and complete corrective messages about the issues discussed in this letter to the audience(s) that received the violative promotional materials. Please direct your response to me at the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, 5901-B Ammendale Road, Beltsville, MD 20705-1266, facsimile at:301-796-9877. In all future correspondence regarding this matter, please refer to the MACMIS #15909 in addition to the ANDA number. We remind you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that all your promotional materials comply with each applicable requirement of the Act and FDA implementing regulations.

Failure to correct the violations discussed above may result in FDA regulatory action, including seizure or injunction, without further notice.

Sincerely,

/S/

Thomas W. Abrams, R.Ph., M.B.A.
Director
Division of Drug Marketing,
Advertising, and Communications

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1 A June 12, 2007, press release from Sciele Pharma, Inc., (found on the Internet at http://phx.corporate-ir.net/phoenix.zhtml?c=120763&p=irol-newsArticle_print&ID=1014610&highlight=) announced that Sciele Pharma, Inc. had completed its acquisition of Alliant Pharmaceuticals, Inc. and indicated that Alliant and Morton Grove terminated the agreement between the two companies pursuant to which Alliant marketed lindane. The websites promoting Lindane Shampoo were available for several weeks following this press release.

2 FDA staff last accessed the Alliant website on August 8, 2007 and the Lindane Shampoo website on July 2, 2007. We note that both the Lindane Shampoo website [http://www.lindane4lice.com] and the Alliant website [http://www.alliantpharma.com] can no longer be accessed through these URLs.

3"FDA Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice," dated March 28, 2003, FDA's Drug Information Page on Lindane, located at http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm (PHA).

4"FDA Talk Paper -- FDA Issues Health Advisory Regarding Labeling Changes for Lindane Products," dated March 28, 2003, FDA's Drug Information Page on Lindane, located at http://www.fda.gov/bbs/tonics/ANSWERS/2003/ANSO1205.html (Talk Paper).

5"FDA Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice," dated March 28, 2003, FDA's Drug Information Page on Lindane, located at http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm (PHA).

6 Brandenburg K, Deinard AS, DiNapoli J, et al. 1% permethrin cream rinse vs 1% lindane shampoo in treating Pediculosis captitis. Am J Dis Child. 1986;140(9):894-896.

7 See, e.g., Meinking, TL, Am J Manag Care. 2004 Sep;10(9 Suppl):5264-8; Meinking TL, Taplin D. Advances in pediculosis, scabies, and other mite infestations. Adv Dermatol. 1990;5:131-50. The authors of this 1990 publication concluded that considerable evidence had accumulated indicating that lice can become tolerant or resistant to lindane.

8 Burkhart, et al., Expert Opin Drug Saf 2006;5(1):173.

Protect Children From Pharmaceutical Lindane!

Michigan Network for CHILDREN'S Environmental HEALTH

Lindane is the active ingredient in some products used to treat head lice and scabies. Health professional organizations throughout Michigan have supported action to phase out pharmaceutical use of lindane in Michigan. HB 4402 allows use of lindane in pharmaceutical products in Michigan only under the supervision of a physician in his or her office.

What do government agencies and experts say about lindane?

Michigan Department of Community Health:

- "The Michigan Department of Community Health **does not recommend** the use of Lindane to treat scabies patients."[1]
- The same is true for head lice: "The State of Michigan **does not recommend** using Lindane."[2]

Health professional organizations in Michigan have supported a lindane phase-out:

- Michigan Chapter of the American Academy of Pediatrics
- Michigan Council for Maternal and Child Health
- Michigan Council of Nurse Practitioners
- Michigan Nurses Association
- Michigan Pharmacists Association
- Michigan Association of School Nurses
- Wayne County Medical Society of Southeast Michigan

U.S. Food and Drug Administration (FDA):

- In 2003, the FDA released a public health advisory for lindane. It cited a variety of concerns, including: "In post-marketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among adverse events reported in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia."[3]
- The Agency issued nearly identical Black Box Warnings for lotions and shampoos containing lindane in 2003: "Lindane lotion should be used with caution for infants, children, the elderly, and individuals with other skin conditions (e.g. atopic dermatitis, psoriasis) and in those who weigh <110lbs (50 kg) as they may be at risk of serious neurotoxicity."[4]
- An internal FDA assessment concluded: "Lindane was labeled a second line therapy in 1995 because, while it is similar in action to other approved therapies, it has a higher percutaneous absorption than other approved scabicides and pediculocides. This greater systemic exposure may translate to a greater potential for serious adverse events."[5]

State of California:

- "Commencing January 1, 2002, any product used for the treatment of lice or scabies in human beings that contains the pesticide Lindane shall not be used or sold in the state."[6]
- "The main source of Lindane in sewers is from the treatment of head lice and the treatment of scabies, which is a mite that can live in human skin."[7]

U.S. Environmental Protection Agency (EPA):

- "Since 1998, the registrants have voluntarily cancelled a large number of Lindane uses, including direct treatment of livestock, pet products, ornamentals, home lawns, fallow

areas, commercial food processing facilities and storage areas, greenhouses, wood treatment, forestry, Christmas tree plantations, **military use on human skin and clothing**...."[8]

- The U.S. EPA classifies lindane as one of twenty-two "Bioaccumulative Chemicals of Concern" in the Great Lakes.[9] New discharges of these chemicals are prohibited into "mixing zones" due to "continuing evidence that the highly bioaccumulative nature of these toxic chemicals presents a significant potential risk to human health, aquatic life and wildlife."[10]
- Since 1988, the U.S. EPA has classified lindane as an "Extremely Hazardous Substance" in Section 302 of the Emergency Planning and Community Right-to-Know Act.[11, 12]
- The U.S. EPA classifies lindane as a "Priority Pollutant" under the Clean Water Act "for the protection of aquatic life and human health in surface water...."[13]
- Lindane is included in the U.S. EPA's Toxic Release Inventory (TRI) Program,[14] which "requires facilities in certain industries, which manufacture, process, or use significant amounts of toxic chemicals, to report annually on their releases of these chemicals."[15]
- "Lindane and the other HCH isomers are mobile in the environment, and through long-range atmospheric transport, are deposited in the Arctic, where they have been detected in air, surface water, groundwater, sediment, soil, ice, snowpack, fish, wildlife, and humans."[16]
- All uses except pharmaceutical uses are now restricted. "On August 2, 2006, EPA announced that registrants Chemtura USA Corporation, followed by AGSCO Inc, Drexel Chemical Co., and JLM Industries, Inc., requested to voluntarily cancel all remaining pesticide registrations of the organochlorine pesticide lindane. EPA also has made a determination that the remaining uses of lindane are not eligible for re-registration."[17]

U.S. Agency for Toxic Substances and Disease Registry (ATSDR):

- The U.S. ATSDR ranks lindane 32nd of the 275 substances on its list of CERCLA (Superfund) "Priority Pollutants."[18] This list reflects a "prioritization of substances based on a combination of their frequency, toxicity, and potential for human exposure at NPL [National Priorities List] sites."[19]

International actions on lindane:

- "...Lindane is banned for use in 52 countries, [and] restricted or severely restricted in 33 countries."[20]
- The International Agency for Research on Cancer (IARC), the premier agency on carcinogen classification, currently considers hexachlorocyclohexanes, the class of chemicals to which lindane belongs, as "possibly carcinogenic to humans."[21]
- The United Nations Environment Programme announced the nomination of lindane to become one of five new contaminants to be added to the original 12 in the Stockholm Convention on Persistent Organic Pollutants (POPS): "Mexico is nominating the pesticide lindane together with a related group of chemicals known as hexachlorocyclohexanes. It explains that producing the 99%-pure gamma hexachlorocyclohexane needed for every ton of lindane results in six to ten tons of unusable isomers. The resulting wasteisomer problem compounds the risks posed by lindane itself."[22]
- The Rotterdam Convention adopted in 1998 includes lindane among the 39 pesticides and industrial chemicals banned or severely restricted for health or environmental reasons by participating parties.[23]

Expert Opinions:

Jim Gulliford, assistant administrator for EPA's Office of Prevention:

- "Jim Gulliford, assistant administrator for EPA's Office of Prevention, called lindane 'one of the most toxic, persistent, bioaccumulative pesticides ever registered.'"[24]

Ann Heil, Senior Engineer, Los Angeles County Sanitation Districts:

- "Lindane can contaminate water resources, especially when its use is widespread. A single head lice or scabies treatment can contaminate 6 million gallons of water - and cost an average of $4,000.00 to remove from wastewater."[25]

These quotations were compiled by the Michigan Network for Children's Environmental Health, 117 N. Division St., Ann Arbor, MI 48104, 734-761-3186 x115, healthykids@mnceh.org, www.mnceh.org. Emphasis was added by MNCEH.

REFERENCES:

1 Michigan Department of Community Health. *Scabies Prevention and Control Manual.* Version 1.0. May 2005. Accessed 12-22-06 at: www.michigan.gov/documents/BHS_NHM_Michigan_Scabies_Prevention_and_Control_Manual_131983_7.pdf.

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ENVIRONMENTAL HEALTH PERSPECTIVES

Environmental Health Perspectives Volume 116, Number 3, March 2008, Science Selections

Life after Lindane in California

Water Concentrations, Poison Control Calls Drop Following Ban

Lindane, a persistent, highly toxic, and bioaccumulative organochlorine insecticide, was used in agriculture and as a topical treatment for human head lice and scabies beginning in the 1940s. As its toxicity became better known, manufacture and use declined in the United States; in 2002, California banned the pharmaceutical use of lindane altogether. According to a new study, that ban appears to have resulted in steep drops in concentrations of lindane in Southern California's wastewater and a dramatic reduction in calls to the California Poison Control System [EHP 116:297–302; Humphreys et al.].

The most common adverse effects of lindane exposure in humans include seizures, dizziness, and headaches. High levels of exposure can be fatal. Although the U.S. Environmental Protection Agency has canceled all registrations for lindane-containing compounds in agriculture, the chemical is still available by prescription as a second-line treatment for head lice in states other than California. Its continued pharmaceutical use raises concerns about its potential presence in wastewater effluent and drinking water.

The research team, part of the University of California, San Francisco, Pediatric Environmental Health Specialty Unit, examined historical lindane concentrations in several Southern California water pollution control plants and compared them before and after the ban. To assess the ban's impact on human exposures, they analyzed lindane-related calls to California's poison control hotline between 1998 and 2006. They searched the Medi-Cal fee-for-service pharmacy-paid claims database and obtained national data from Verispan, a commercial health industry data tracker, to determine the number of lindane prescriptions issued. The team also conducted a random survey of pediatricians to ascertain both their awareness of the ban and their current treatment preferences for scabies and head lice.

In Los Angeles County, the average wastewater concentration of lindane in 1999 was 36 ppt. By 2006, concentrations had dropped to almost undetectable levels throughout California. In 1998, 135 per 100,000 calls to the Poison Control System concerned lindane; by 2006 such calls had declined to 2 per 100,000. Similarly, lindane prescriptions fell from 114,000 in 1997 to 34 in 2002. Medical providers reported few problems using alternative treatments such as pyrethrins.

The study authors are encouraged by their findings but note that lindane is still used in many countries, mostly in the developing world, and that every ton of lindane manufactured produces about 9 tons of toxic waste. Although the U.S. Food and Drug Administration has not banned pharmaceutical lindane in the United States, the pesticide is currently under review for inclusion in the Stockholm Convention on Persistent Organic Pollutants, which could eventually lead to a worldwide ban.

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October 6, 2006

Dear Michigan Legislators,

Support Pharmaceutical Lindane Ban (HB 5574)

I am writing to express support for HB 5574, which would ban the use of pharmaceutical lindane in Michigan. As background, I am a registered professional chemical engineer in the State of California, with seventeen years of experience in the wastewater field. I have a Bachelor's Degree from the University of Michigan and a Master's Degree from Caltech, both in chemical engineering. I am currently employed by the Sanitation Districts of Los Angeles County, where my responsibilities have included conducting source control for residential and commercial sources, with a focus on chlorinated solvents, pharmaceuticals, pesticides, chlorides, and mercury. I was named Pollution Prevention Advocate of the Year for 2000 by the Western Regional Pollution Prevention Network and Industrial and Hazardous Waste Control Person of the Year for 1999 by the California Water Environment Association. My projects have earned numerous awards including the National Pollution Prevention Roundtable's First Place Most Valuable Pollution Prevention Award. In 1998 I initiated a public outreach program to reduce pharmaceutical uses of lindane, and this program later led to a ban in California on pharmaceutical usage of lindane. As part of this program, I conducted extensive research into uses and effects of lindane.

As you may be aware, lindane is highly neurotoxic pesticide that is readily absorbed through the skin. Pharmaceutical lindane is used to treat head lice and the skin mite scabies. When lindane is used to treat head lice, it is applied to the scalp and allowed to sit for ten minutes before rinsing. When lindane is used to treat scabies, it is applied to the entire body, except for the face and scalp, and allowed to sit in contact with the skin for eight hours. Because of the long contact time with skin and the large surface area to which it is applied, treatment with lindane for scabies in particular results in a high percentage of absorption of lindane by the body. While most parents would never consider spraying their children with common household pesticides, application of lindane to treat head lice and scabies is essentially the equivalent, although lindane is much **more** toxic than common household pesticides such as RAID.

The State of California passed a law in 2000 (Assembly Bill 2318) that banned the sales and use of lindane to treat head lice and scabies as of January 1, 2002. I provided testimony and technical expertise during consideration of this bill. The law was passed due to both human health concerns and environmental concerns. The human health concerns are obvious, and the medical literature is clear that other treatment for lice and scabies are just as effective, or more effective, and less toxic than lindane. As to environmental concerns, when lindane is used to treat head lice or scabies it is rinsed down the drain after application. It travels through sewers to the downstream wastewater treatment plant, but wastewater treatment plants only remove about one-fourth of the lindane in wastewater. The rest passes through to the creek, river, lake, or other

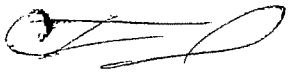
water body downstream of the treatment plant. Because lindane is a persistent, bioaccumulative, and toxic pollutant, it can build up in the environment and move up the food chain. A single head lice or scabies treatment contains enough lindane to pollute six million gallons to the water quality standards set for California for existing and potential drinking water sources.

Since the California pharmaceutical lindane ban took effect over four years ago, lindane levels in both wastewater and in receiving waters downstream of wastewater treatment plants in California have dropped dramatically. Two years ago I spoke to public health officials, prison systems officials, and representatives of both pharmaceutical and medical trade associations. At that time, none reported any adverse impacts from the pharmaceutical lindane ban. In fact, many parties I contacted indicated that they had stopped using lindane long before the ban was passed.

Based on the experience in California, I highly recommend that you pass HB 5574, which would enact a similar ban in Michigan. There is no reason that the waters of Michigan should not be protected to the same degree as the waters of California. Having grown up in Michigan and attended the University of Michigan, I am well aware of the quality and variety of Michigan's lakes, streams, and creeks, and would like to see them protected.

Please feel free to contact me if you have any questions or would like further information.

Very truly yours,



Ann Heil

Lindane in the Great Lakes

Michigan Network for CHILDREN'S Environmental HEALTH

Lindane is a pesticide used in certain pharmaceutical treatments for children's head lice and for scabies. The U.S. EPA classifies lindane as one of 22 "**Bioaccumulative Chemicals of Concern**" in the Great Lakes,[1] as a "priority pollutant" under the Clean Water Act,[2] and as an "**Extremely Hazardous Substance.**"[3] Lindane is no longer used in the U.S. for agricultural, veterinary, or military purposes. Although the majority of lindane was used in agriculture, all forms of lindane are persistent, bioaccumulative, and toxic. Support HB 4402 to restrict pharmaceutical use of lindane!

Lindane is Commonly Found in the Water of Lake Huron

- **Lindane is present in Lake Huron, Erie, Superior and Ontario water,** according to a 2007 EPA and Environmental Canada "State of the Great Lakes" report.[4] **Lindane was "commonly found" in Lake Huron.**

Lindane is in Michigan Sewage Systems

- The Detroit Wastewater and Sewerage Department found **detectable levels of lindane** in leachates prepared from solid residuals of wastewater during the sewage treatment process. Lindane was found in the grit, scum, and filter press cake from 2002 to 2004. Levels ranged from 0.01 to 0.89 ug/L (micrograms per liter or parts per billion) in the leachates.[5] **Lindane in the Detroit Wastewater system is likely the result of pharmaceutical uses of lindane.**

Lindane is in Great Lakes Fish and Mussels

- "The most recent years of available analytical data in the U.S. EPA's Great Lakes Fish Monitoring Program indicate the concentration of **lindane in sport fish fillets** (Chinook and Coho Salmon and Steelhead Trout) have ranged between trace detection and 0.005 ppm between 1982 and 2000."[6]
- The National Oceanic and Atmospheric Administration's National Status and Trends Program has found gamma-hexachlorocyclohexane **(lindane) in the tissues of mussels in the Great Lakes at "high concentrations"** in at least one site from 1992 until the latest data available (2005).[7]

Lindane is Found in the Air in the Great Lakes Region

- "**Lindane** is being monitored **in air and precipitation** with the Integrated Atmospheric Deposition Network **in the Great Lakes region** with average concentration of 15-90 pg/m3 in the early 90s, decreasing to 5-30 pg/m3 since 2000."[9]

Lindane is Present at Contaminated Sites in Michigan

- Lindane has been identified in 189 of the EPA's National Priorities List of hazardous waste sites (Superfund sites). At least twelve of these sites are located in Michigan.[10]
- The Michigan Department of Environmental Quality has **found lindane at three of its contaminated (Part 201) sites:**[11] Grand Blanc (Genesee County), Rhodes (Gladwin County), and Scottville (Mason County).

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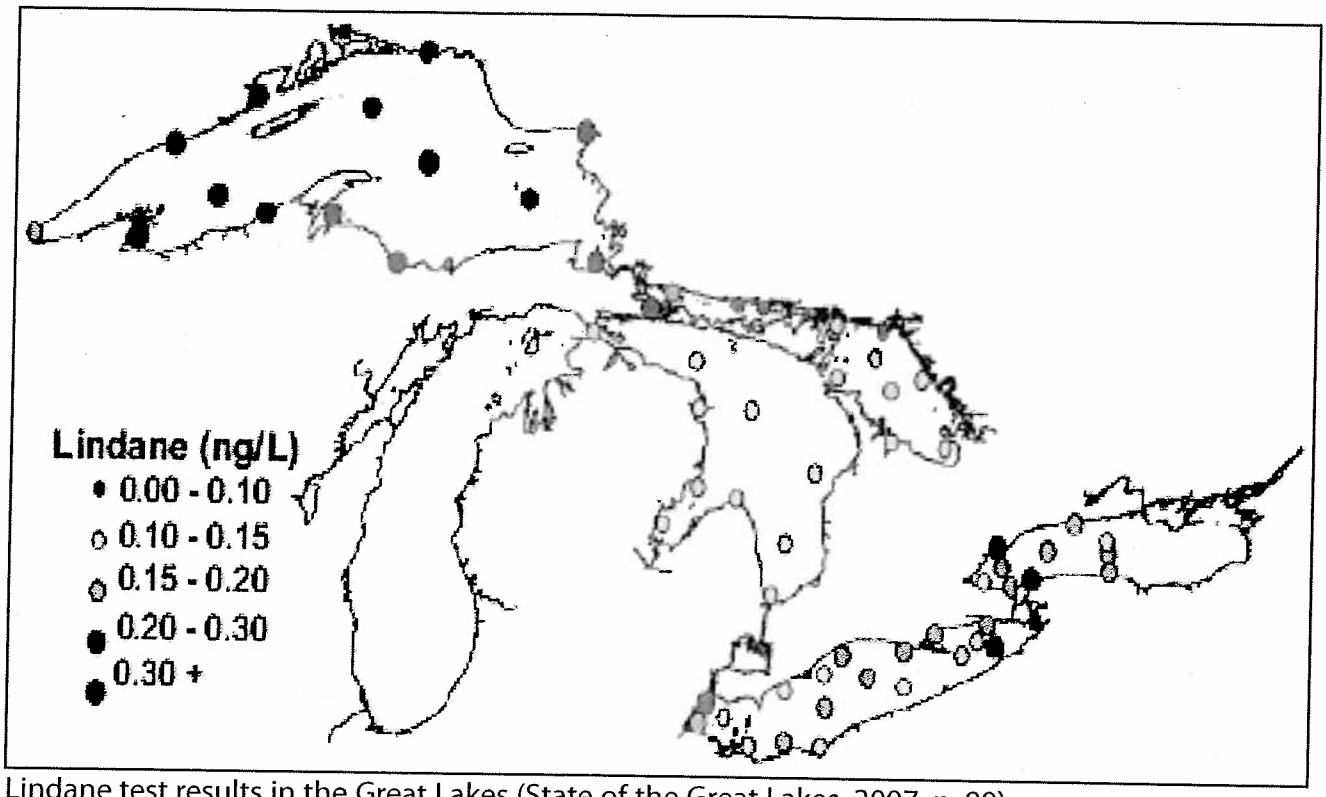

Lindane test results in the Great Lakes (State of the Great Lakes, 2007, p. 99)

Emphases throughout document added by the Michigan Network for Children's Environmental Health

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Michigan Network for
CHILDREN'S
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HEALTH

FDA
Resources

1. Public Health Advisory on Lindane
2. Warning on Lindane for Scabies and Lice from FDA Patient Safety News
3. FDA versus EPA Exposure Chart

FDA Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice

The Food and Drug Administration (FDA) has issued a Public Health Advisory (PHA) concerning the use of topical formulations of Lindane Lotion and Lindane Shampoo for the treatment of scabies and lice. In addition to this PHA:

- The boxed warning emphasizes that it is a second-line treatment, updates information about its potential risks especially in children and adults weighing less than 110 pounds, and reminds practitioners that reapplication of Lindane Lotion or Lindane Shampoo is not the appropriate treatment, if itching continues after the single treatment.
- Lindane product package sizes will be limited to 1 and 2 ounces in order to minimize the potential for patients to apply the product in excess and to minimize reapplication of Lindane. Pharmacists should dispense a quantity sufficient for a single treatment, not to exceed 2 fluid ounces.
- A Medication Guide, designed to inform patients of the risks of Lindane products and provide instructions for appropriate use of the drugs, must now be dispensed by the pharmacist with each new prescription.

Lindane Products are Second-Line Treatments for Scabies and Lice

Lindane (gamma-hexachlorocyclohexane) is approved for topical treatment of pediculosis and scabies in patients "who have either failed to respond to adequate doses, or are intolerant of, other approved therapies." Lindane has been on the market since 1951, but was labeled as second-line therapy in 1995 because there are safer alternative treatments that should be used first. Second-line therapy is defined as:

1. The patient cannot tolerate the first-line drug of choice or
2. The patient has used the first-line drug of choice as instructed and the treatment has failed.

Examples of other medications approved to treat scabies and lice include the following:

Scabies:	permethrin cream 5% (Acticine, Elimite, Nix)
	crotamiton cream (Eurax)
Lice:	malathion lotion 0.5% (Ovide, prescription only)
	pyrethrum 0.33% with piperonyl butoxide shampoo and cream rinse
	permethrin cream rinse 1% (Nix and Rid)

Current Issues

FDA has determined that Lindane products have benefits that outweigh risks when used as directed. Most serious adverse events reported in association with Lindane products have been due to misuse. However, there have been rare case reports of serious reactions with apparently normal use. These reports highlight the need to emphasize the potential toxicity of Lindane in the product labels and educate healthcare providers and patients about the risks and how to minimize them, as well as to develop mechanisms to facilitate safe use, once the drug is dispensed to patients. These mechanisms include having Lindane products available only in small packaged amounts to avoid excess application and requiring that the Medication Guide be given to the patient by the pharmacist with each new prescription.

Current Safety Information

Safety information for Lindane comes from the FDA's Adverse Event Reporting System (AERS), which is derived from spontaneous adverse event reports through FDA's MedWatch Program and literature reports submitted to the Agency. Rates of adverse events cannot be calculated from this system and underreporting is presumed, especially for older products like Lindane Lotion and Shampoo.

The adverse events of concern for Lindane are systemic events due to absorption of this lipophilic drug following topical application. The majority of events occurred in patients with contraindications to the use of Lindane, in patients who used the medication in excessive amounts, or in those who misused the Lindane product. Of the adverse event cases in the FDA database with a serious outcome (hospitalization, disability or death), only 20% used Lindane according to the directions in the label. All other patients did not use Lindane according to directions in the label. Most commonly, patients often reapplied Lindane because of continued itching after the treatment, either on their own volition or at their doctor's recommendation.

Deaths

Three deaths due to Lindane use have been confirmed, although 17 deaths have been reported associated with Lindane use. The three confirmed deaths all included use of Lindane not in accordance with the label, including multiple topical applications or oral ingestion. Lindane toxicity was confirmed by autopsy in a child, and was diagnosed in an adult. The third death occurred in an adult who ingested Lindane for suicide purposes.

Of the remaining 14 deaths associated with Lindane, but not confirmed, there were 4 children, 9 adults and 1 patient of unknown age. All of these deaths occurred when Lindane was applied topically. In 9 cases, use was not in accordance with

the label (exceeded label use - 7, oral administration – 1, use was contraindicated - 2). Scabies and head and/or pubic lice were the predominant indications for use.

Neurologic Risks

The risk of neurologic side effects associated with Lindane is known from clinical trials, spontaneous post-marketing reporting data and literature reports. These side effects have ranged from dizziness to seizures. In post-marketing reports, neurologic side effects occurred in patients who misused Lindane, as well as in patients who used Lindane according to labeled instructions. Among the adverse event reports in the FDA database, 70% reported neurologic events including seizure, dizziness, headache and paresthesia.

Increased Risk in Younger and/or Smaller Patients and the Elderly

Lindane is contraindicated for use in neonates and should be used with extreme caution in children and in individuals weighing less than 50 kg (110 lbs). Among adverse event reports in which the outcome was serious (resulted in hospitalization, disability or death), the very young and the elderly appeared to be more susceptible to Lindane's adverse effects and had worse outcomes.

Animal studies have demonstrated that younger animals are more susceptible to the neurologic side effects seen with Lindane use. In addition, smaller children have a larger body surface to volume ratio that may result in proportionately larger risk of systemic exposure. For this reason, Lindane has long been contraindicated for use in neonates. It is not known whether the developing nervous system of children also increases their susceptibility to neurologic toxicity.

Other Populations with Increased Risk

Patients who have conditions, such as HIV infection, or take certain medications that may lower the seizure threshold should be prescribed Lindane with caution. They may be at greater risk for serious adverse events. The new Lindane label lists examples of some of these conditions and medications. The label also highlights special precautions for use of Lindane in women who are breastfeeding infants.

There are case reports of neurologic adverse events in nursing home patients treated with Lindane. Factors that may have increased their susceptibility to these adverse events include concomitant medications, underlying medical conditions, and advanced age. Special consideration should be given prior to treating this population with Lindane, even if they are greater than 50 kg.

Conclusion

Lindane products should be prescribed carefully, and quantities prescribed should be limited to amounts for a single application. Patients are at risk for serious neurologic adverse events, and even death, particularly with early retreatment. It is not known how soon after administering one dose of Lindane that a second dose can be safely administered. Post-treatment itching is common, especially in the treatment of scabies and does not necessarily indicate treatment failure.

The instructions for Lindane use have been clarified in the products' professional labels and in the Medication Guides, which by law must be dispensed with all prescriptions of lindane. Because most of the serious adverse events reported

have been because of misuse of Lindane Lotion and Lindane Shampoo, it is very important that patients understand the importance of using this medication in a manner consistent with product labeling.

The FDA wants healthcare providers to be aware of this new safety information and the changes that have occurred in the label for topical Lindane Lotion and Lindane Shampoo prescribed for the treatment of scabies and lice (both head and pubic lice), respectively. Healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug sequelae.

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FDA/Center for Drug Evaluation and Research
Last Updated: March 28, 2003
Originator: OTCOM/DLIS
HTML by SJW

June 2003 FDA Patient Safety News Homepage
Warning on Lindane for Scabies and Lice

In a recent Public Health Advisory, FDA warned health professionals and consumers about the potential toxicity of Lindane when it's used to treat scabies and lice. FDA has reports of neurologic effects from topical Lindane products, ranging from dizziness to seizures, as well as several deaths. Most of the serious effects were due to misuse of the products, but there have been rare case reports of serious reactions from apparently normal use.

The FDA advisory stresses that Lindane is a second-line treatment. It should be prescribed only when the patient doesn't respond to safer treatments, such as permethrin or malathion products, or if the patient can't tolerate these safer products.

Many of the serious adverse events reported to FDA occurred when the medication was applied several times. And so the FDA advisory says that patients should be instructed that Lindane products should be applied just once. Patients should understand that itching after treatment may be due to the Lindane itself rather than the scabies or lice, and shouldn't be tempted to reapply the medication.

The FDA advisory also advises special caution in prescribing Lindane products for specially susceptible population groups. These include patients weighing less than 110 pounds, the elderly, those with HIV infections, and those on medications that may predispose them to seizures. And Lindane products are contraindicated in neonates.

FDA is requiring a new boxed warning on the packaging of Lindane products describing these precautions. And the package sizes of Lindane products will

be limited to one and two ounces, to help prevent patients from reapplying the medication. Pharmacists should dispense only enough of the product for a single treatment, not to exceed two ounces. And pharmacists must provide a Medication Guide to the patient with each new prescription. The Guide describes the risks of Lindane, and gives instructions for appropriate use.

Additional Information:
FDA/Center for Drug Evaluation and Research: Lindane Shampoo and Lindane Lotion.
http://www.fda.gov/cder/drug/infopage/lindane/default.htm
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=16#6

EPA and CDER/FDA Approaches to Acceptable Exposure to Lindane 12 pm version 7/16/02 lindantech.doc

Approach or study	EPA Approach/Assumptions/Interpretation	FDA Approach/Interpretation	Uncertainties/Confounding factors
General approach	Therapeutic benefit is not considered A NOAEL is determined in the most sensitive species A quantitative risk assessment is conducted based on the NOAEL A reasonable certainty of no harm requires a target safety margin of exposure (MOE) of 100	Risk is evaluated with respect to the benefit obtained by the patient. This risk/therapeutic benefit is considered paramount. A quantitative risk assessment is not conducted.*see note 1. Other available therapies considered. *see note 2. Animal data should be from studies with the same route and duration of exposure Nonrodent also tested; most relevant species is used Human safety data supercede animal toxicity data Human exposure is determined under conditions of use with the clinical formulation. *see note 3. Thresholds for toxicity are considered Very large (>10x) safety factors are not generally used Minimal reversible toxicity could be considered acceptable	
Acute oral neurotoxicity in immature (4- to 5-wk old) rats	The NOAEL for behavioral effects is 6 mg/kg Assumes sensitivity of rats and humans to lindane effects is similar This value will be used for extrapolation to humans	Data were highly variable; 20 mg/kg could be considered the NOAEL for behavior, and effects were reversible; however 60 mg/kg caused convulsions, so for purposes of extrapolation 1/10 a convulsive dose could be used. The animals were immature (more sensitive to lindane) and not adult The exposure was by gavage and not dermal; The neurotoxic effects could be exaggerated when the entire dose is given once, yielding a higher Cmax, rather than over a multi-hour period A steep dose response exists between no effects and convulsions	Young animals exposed by gavage would probably result in a lower NOAEL than dermal exposure in adult animals
Dietary multidose in rabbits (gestation day 6 through lactation day 10)	NOAEL for pup effects is 1.2 mg/kg/d maternal exposure NOAEL for maternal effects is 5.6 mg/kg/d Pup NOAEL could be used for extrapolation to humans	Pregnant women should not use lindane Multi-dose exposure increases toxicity Exposure is dietary and not dermal Exposure of pups to lindane is unknown and cannot be determined from maternal exposure Lindane could accumulate in fetus and pups would also be exposed in the milk. Higher conc of lindane in fetal blood than in maternal blood and in fetal tissue than in maternal fat.	Multi-dose studies will result in a lower NOAEL than single dose studies. Since pup exposure is not known, quantitative extrapolations not possible without further information. NOAEL in pups should not be used to determine risk in adults.

EPA and CDER/FDA Approaches to Acceptable Exposure to Lindane (b)

Approach or study	EPA Approach/Assumptions/Interpretation	FDA Approach/Interpretation	Uncertainties/ confounding factors
Single dermal exposure of 60 mg/kg in 1-kg weanling rabbits caused convulsions Lindane in blood 24 hr later at time of convulsions was 0.7-2.5 ug/ml		Immature animals more sensitive to lindane than young adult animals	Effects in weanling cannot be extrapolated quantitatively to effects in adults
13-week neurotoxicity study in rabbits		Lindane accumulates (10x) in the brain, as well as in adipose tissue	Plasma levels may not reflect brain levels
320 ng/ml plasma 4 hr after oral ingestion associated with convulsions in a child	This value could be compared to values after appropriate clinical use	Effects are in a child and not in an adult Effects may be attributed to higher than measured blood levels; 4 hours could be after the rapid distribution phase Effects would correlate with brain levels The highest no effect level is not known Other components in the product when ingested may lower the threshold for lindane toxicity	Children are more sensitive than adults Other components in the product when ingested may lower the threshold for lindane toxicity Plasma levels associated with causation of the toxic effects are not known. *See note 4
Dermal bioavailability of lindane lotion in monkeys after 24–hr exposure is 20%	The value of 20% could be used in extrapolation from an oral study to human dermal exposure	24-hr exposure exceeds labeled use of 8-12 hr.	20% dermal bioavailability estimate is probably on the high side; 8-10% is quoted from human studies that did not use the marketed formulation.
Dermal bioavailability of a pesticide formulation is 10% in humans		Dermal bioavailability of lindane lotion is unknown and depends on the formulation 10% could be considered a reasonable estimate	Dermal bioavailability of lindane lotion under conditions of use is unknown
Max Plasma level after whole body exposure to lotion for scabies is 64 ng/ml (mean is 29 ng/ml)	A 4x adjustment should be made because old labeling allows patients to use more than the amount used in the study	Application of the lotion was preceded by a warm bath that increased dermal bioavailability and which is counter to labeling Entire body was covered, so no adjustment is necessary Revised labeling will reduce the amount available for application	EPA estimate of human exposure under conditions of use may be higher than actual. *see note 5.

EPA and CDER/FDA Approaches to Acceptable Exposure to Lindane (c)

Approach or study	EPA Approach/Assumptions/Interpretation	FDA Approach/Interpretation	Uncertainties/ confounding factors
Production volume of lindane pharmaceutical formulations = at least 50, 000 gallons per year		The number of persons using lindane for scabies is unknown and can only be estimated within an order of magnitude	
Adverse Event Reporting: Most effects associated with misuse or nonlabeled use		Most persons have no detectable serious effects Limited product size, revised labeling and increased warnings plans were conveyed to generic companies to further reduce risk. Dose-ranging studies are proposed to determine if lower dose and duration of application for scabies would still be effective	EPA used current labeling and considered effects on children *see note 6 and 7

Note 1: The Food and Drug Administration approves drugs based on a risk/benefit analysis. A drug must be determined to be safe and effective for a specific population with a specific condition at the dose described in the label. The FDA recognizes that all drugs have associated risks, and determines if the risk is acceptable when compared to non-treatment of the condition. The FDA has determined that there are other therapies for the treatment of head lice and scabies that may have less risk associated with them, and thus, the label states that lindane should be reserved for patients, "who have either failed to respond to adequate doses, or are intolerant of, other approved therapies." These patients would have documented failed prior treatment with other approved products, or documented reactions – either local or systemic, to those products or drugs that would be expected to cross-react with those products. For the indication of scabies, alternative therapies are limited.

Note 2: Resistance to products must be considered when evaluating pesticides. At this time, there is documented resistance to Lindane, which has been available since 1947. It should be noted that there is not resistance to permethrin noted in the literature to date for permethrin, but with increased usage, there is a likely possibility that this will occur. In addition, there are documented cases of resistance to all treatments that are currently indicated for the treatment of head lice.

Note 3: The human exposure from the Ginsburg study is per labeled instructions. This study was performed on pediatric patients who had a warm soapy bath prior to application which may have increased systemic absorption.

Note 4: It is important to note that the 320 ng/ml plasma level from the Aks article, as well as the 290 ng/ml plasma level in the PDR, are plasma levels that were obtained several hours after acute ingestion of the lindane product. The plasma levels provide a tool to determine the etiology of a patient's seizure upon presentation to the Emergency Room but are not a NOAEL. This information is helpful to a physician in determining if the patient's seizure was secondary to lindane ingestion, or if there is another etiology. The data for lindane indicate that there is a two-compartment pharmacokinetic model. After ingestion, there is a steep rise in the serum level, followed by a rapid decline during the disposition phase when some lindane distributes to lipid tissues and some is excreted. The disposition phase is followed by a prolonged beta elimination phase. Based on this model, it is probable that the patient's symptoms (seizure) occurred at a higher serum level than those levels obtained 4 hours after the initial ingestion.

The marketed formulation has other ingredients that may contribute to the toxicity in acute ingestions. Ingredients for lotion include: glycerol monostearate, cetyl alcohol, stearic acid, trolamine, carrageenan, 2-amino-2-methyl-1-propanol, methylparaben, butylparaben, perfume and water. Ingredients for shampoo include: glycerol monostearate, cetyl alcohol, stearic acid, trolamine, carrageenan, 2-amino-2-methyl-1-propanol, methylparaben, butylparaben, perfume and water.

Note 5: Current labeling includes the following information regarding amount of lindane to be applied, "USE ONLY ENOUGH TO COVER THE BODY IN A THIN LAYER. 1 OUNCE (HALF OF A 2 OUNCE CONTAINER) SHOULD BE ALL THAT IS NEEDED FOR CHILDREN UNDER 6 YEARS OF AGE; 1 TO 2 OUNCES FOR OLDER CHILDREN AND ADULTS." The new labeling will exclude the volume to be applied and will describe application as a thin layer. In addition, only 1-ounce bottles of lindane will be available. For adult patients, physicians will have to write a prescription for two 1-ounce bottles to be dispensed, and the pharmacist will dispense two 1-ounce bottles.

Note 6: New labeling will restrict the use to "patients who have attained adult stature, or approximately 60 kg." This emphasizes that it should not be used in young pediatric patients and that patients should be post-pubescent.

Note 7: The AERS database is a collection of spontaneous, voluntarily submitted reports of adverse events associated with drug products submitted by consumers, healthcare professionals, manufacturers, and others. One of the limitations of a voluntary system of reporting includes a substantial amount of under-reporting. The FDA estimates that between one and 10% of all adverse events are reported to the FDA. Other limitations include the variability in the quality and quantity of information reported. In spite of known limitations, the spontaneous system has value. The system is sensitive to rare, unexpected events, is simple to use, and is relatively inexpensive. In addition, the AERS database does not include the total number of patients who have been treated, with or without adverse events. Because of this, it is not possible to quantify the percentage of patients who have had adverse events.

Michigan Network for
CHILDREN'S
Environmental
HEALTH

Michigan
Department of Community Health
Lindane Recommendations

1. MDCH Lice Manual (Excerpt): "The State of Michigan does not recommend using Lindane."

2. MDCH Scabies Manual (Excerpt): MDCH "does not recommend the use of Lindane to treat scabies patients."

Michigan
Head Lice
Manual

A comprehensive guide to identify, treat, manage and prevent head lice

Michigan Department of Community Health

MDCH

Jennifer M. Granholm, Governor
Janet Olszewski, Director

Keep this out of your house and off your child's head

MICHIGAN Department of Education

Kathleen N. Straus, President
State Board of Education
Thomas D. Watkins, Jr.
Superintendent of Public Instruction

July 2004 – Version 1.0

Prescription Methods

Malathion (0.5%)

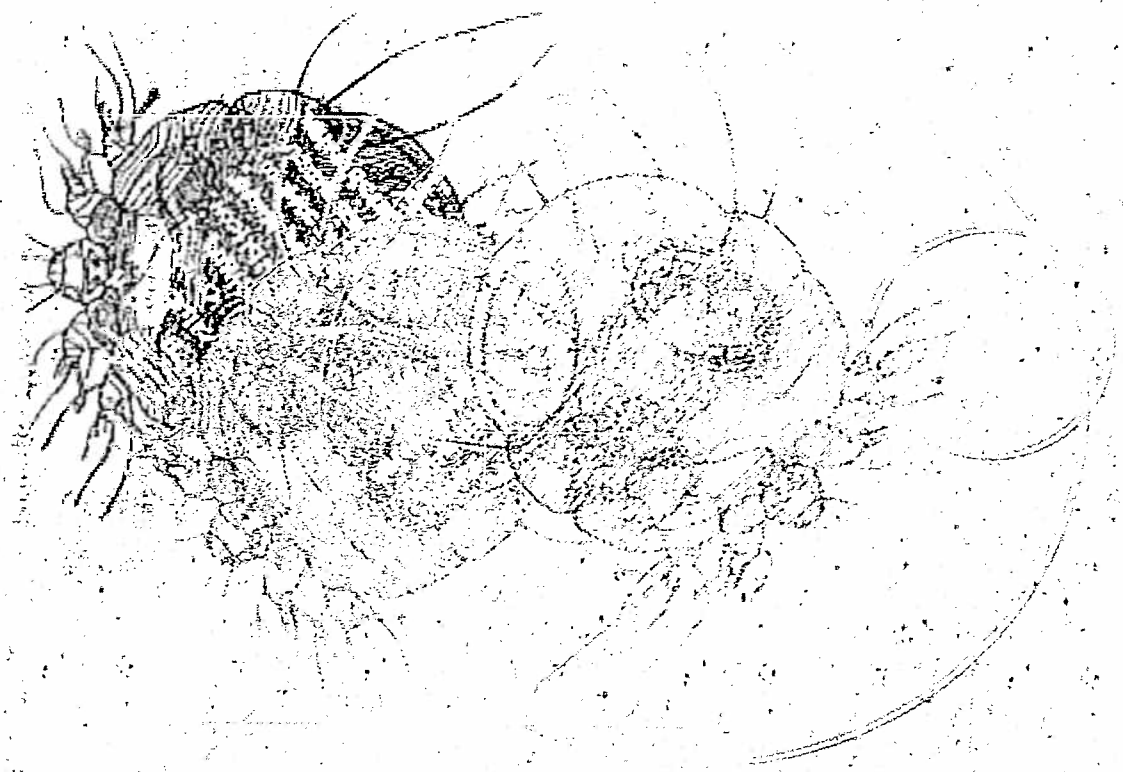
** USE WITH EXTREME CAUTION **

The organophosphate (cholinesterase inhibitor) 0.5% malathion (Ovide) has been reintroduced to the U.S. market and is available by prescription only. The lotion is applied to the hair, left to air dry, then washed off after 8 to 12 hours. Malathion has high ovicidal activity, but the product should be reapplied if live lice are seen in 7 to 10 days. The major concerns about this product include its high alcohol content, making it highly flammable, (users should be instructed not to use hair dryers or curlers or to smoke during the treatment period) and the risk of severe respiratory depression if accidentally ingested. It **should be used with extreme caution** and only in cases where resistance to other products is strongly suspected. Safety has not been established for children under 2 years old.

Lindane (1%)

** NOT RECOMMENDED FOR USE **

Lindane (Kwell) is an organochloride that has central nervous system toxicity in humans if used incorrectly. Several cases of severe seizures in children using lindane have been reported. It is available only by prescription as a shampoo that should be left on for no more than 10 minutes with repeated application in 7 to 10 days. It has low ovicidal activity (30% to 50% of eggs are not killed), and resistance has been reported worldwide for many years. For these reasons, it should be used very cautiously as a last resort. **The State of Michigan does not recommend using Lindane.**



MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

SCABIES PREVENTION AND CONTROL MANUAL

Michigan Department of Community Health

MDCH

Jennifer M. Granholm, Governor
Janet Olszewski, Director

MAY 2005 – VERSION 1.0

Ivermectin (Stromectol)

Ivermectin is an antiparasitic agent that is available as Stromectol from Merck & Co., Inc. This drug has yet to receive approval from the United States Food and Drug Administration for the use in the treatment of scabies infestations; however, recent research has demonstrated that ivermectin is 90% - 95% effective with one dose (200 ug/kg). Questions about dosing this medication should be directed to the facility's pharmacy. It is administered orally, with 8 ounces of water and should be taken one hour before breakfast on an empty stomach. The effectiveness increases to 95% for atypical scabies after two doses.

Pruritus and rash may worsen within the first few days following treatment. Side effects may include cutaneous and/or systemic reactions.

Usage of ivermectin is recommended only for patients in which total body application of other ointments and creams cannot be accomplished (e.g., patients with ventilators, severe contractures, and/or open skin and/or soft tissue lesions, etc.). One dose of ivermectin can be administered in conjunction with a karyolitic agent for treatment of severe crusted scabies. Additional doses at two-week intervals may be needed for immunocompromised patients with crusted scabies.

10 % Crotamiton (Eurax)

Crotamiton lotion (Eurax, Westwood-Squibb Pharmaceuticals, Inc.) is approximately 50% - 70% effective in the treatment of scabies. The cream should be massaged into the skin of the whole body. A second application is recommended 24 hours after the first treatment. The body should be washed 48 hours after the last application.

Side effects may include skin irritation, itching, burning, stinging, and rash. The safety and effectiveness in children has not been established. Allergic and irritant dermatitis may occur in some persons. The product should not be used on acutely inflamed or open skin lesions. There are no human or animal data on the safety of this product during pregnancy.

1% Lindane (Kwell)

The Michigan Department of Community Health does not recommend the use of Lindane to treat scabies patients. Previously, 1% Lindane (Kwell, Alpharma USPD Inc.) was the standard treatment for scabies infestations. Lindane is no longer recommended for use due to recent concerns of drug resistance and severe adverse

reactions, including death.

Over-the-Counter Methods

5% - 10 % Sulfur Ointment

The scabies mite can be killed with a 5% - 10% sulfur-based ointment. Sulfur is mixed with petroleum jelly or a cold cream. The mixture is applied to the skin nightly for three nights. The ointment should be thoroughly washed off 24 hours after the last treatment.

The sulfur ointment is an alternative to the previously cited treatments when the other medications cannot be used. Typically, infants less than 2 months old, pregnant women, and nursing mothers cannot use the previously cited treatments.

Side effects can include dry skin and irritation. Persons with hypersensitivity to sulfonamides should not use the ointment.

Benzyl Benzoate

Benzyl benzoate is topical cream that is applied to the skin for 24 hours. After the 24-hour treatment period, the cream should be removed with soap and water. For severe infestation, the cream can be re-applied 24 hours after the initial treatment period. Re-application should occur within five days for the initial treatment. Side effects of this medication include itching and burning.

Post-Treatment Assessment

Symptoms may persist and/or intensify after treatment has been administered due to hypersensitivity to the dying mite. Antihistamines and topical steroid creams (applied after the scabicide has been removed) may be used to alleviate symptoms. Symptoms should gradually improve within 7 to 14 days. Symptoms which persist after this time period may indicate that treatment failure has occurred. Additional treatment efforts should be considered.

Treatment failure leading to persistent scabies infestations may result from any of the following:

- Poor application of scabicide cream
- Failure to identify and treat all scabies cases (including patients, health care workers, volunteers, family, and visitors)

Michigan Network for Children's Environmental Health

— A Brief Overview

Who We Are

- We are a coalition of health professionals, health-affected groups, environmental organizations, and others dedicated to a safe and less toxic world for Michigan's children.

Our Mission

- Through education, outreach, and advocacy, we seek to protect Michigan's children from adverse impacts caused by exposure to widespread hazardous chemicals.

What We Do

- Advocate for policy changes to reduce threats to children's health.
- Educate health professionals and the general public.
- Build the case for broad reform of chemicals regulation to protect Michigan's children.

2009 Campaigns

- Protect children's health by urging Michigan legislators to:
  - Restrict the manufacture and sale of products containing the toxic, persistent flame retardant deca-BDE, a type of flame retardant not covered by current law.
  - Phase out pharmaceutical use of the chemical ingredient lindane in lice and scabies treatments.
  - Phase out mercury-containing products and align state purchasing with a mercury-free goal.
  - Create incentives and authority to promote safer alternatives to hazardous chemicals in consumer products intended for children.
  - Ban the addition of lead to children's products by adopting the American Academy of Pediatrics' recommended threshold of 40 parts per million.
- Advocate for full implementation of the Governor's Executive Directives on Green Chemistry and Environmental Justice. Reduce mercury exposure by eliminating mercury in products and banning incineration or landfilling of mercury-contaminated products.



Michigan Network for CHILDREN'S **Environmental** HEALTH

MEMBER ORGANIZATIONS

- American Academy of Pediatrics (Michigan Chapter)
- Arab Community Center for Economic and Social Services (ACCESS)
- Association for Children's Mental Health
- Autism Society of Michigan
- Citizens for Alternatives to Chemical Contamination
- Clean Water Fund
- Clinton County Family Resource Center
- Detroiters Working for Environmental Justice
- East Michigan Environmental Action Council (EMEAC)
- Ecology Center
- Healthy Homes Coalition of West Michigan
- Learning Disabilities Association (LDA) of Michigan
- Local Motion
- Michigan Coalition for Children and Families
- Michigan Council for Maternal and Child Health
- Michigan Environmental Council
- Michigan League of Conservation Voters Education Fund
- Michigan Nurses Association
- Science and Environmental Health Network
- Voices for Earth Justice

JOIN THE NETWORK

For more information, contact:
Genevieve Howe, Environmental Health Campaign Director, at: 734-761-3186 x 115 or gen@ecocenter.org

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